REMARKS

Claims 34-36 and 46-66 are pending in this application. Claims 49, 52 and 60 has been amended by deleting the phrase "at least one", for clarity. Therefore, no new matter is introduced. The Office Action is discussed below:

Claim Rejections under 35 USC § 112:

On pages 2-6 of the Office Action, the examiner rejects claims 49, 52 and 60 allegedly for failing to comply with written description requirement, and claims 34-36 and 46-66 under enablement grounds. Applicants respectfully disagree with the examiner and refer to the specification for support.

For example, for claim 49, see paragraphs [01], [09], [10], and [13]; for claim 52, see paragraphs [01], [44], [50], and [60]; and for claim 60, see paragraphs [16], [17], [18], and [50]. For clarity, applicants amend the claims by deleting the phrase "at least one". Withdrawal of the new matter rejection is therefore solicited.

Regarding claims 34-36 and 49-66, support can be found throughout the specification, for example, see page 3 paragraph [13] through page 5 paragraph [17], page 6 paragraph [23] through page 7 paragraph [26], and page 11 paragraph [37] through page 16 paragraph [51]. Applicants point out that claim 34 provides a process of making an immunogenic composition, claims 35-36 and 46-66 provides additional materials and/or steps for the claimed process. One skilled in the art would be able to follow the recited steps to practice the claimed invention in view of the specification and based on what is known in the art without any undue experimentation. In this context, the examiner is invited to consider the MPEP:

> Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. Compare *Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 ("one skilled in the art

> who read Rasmussen's specification would understand that it is unimportant how the layers are adhered, so long as they are adhered") (emphasis in original), with *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it"). The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed (see, e.g., *Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).
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> *See* MPEP § 2163 (II)A(2) at 2100-177-178 (Rev. 6, September 2007).

Applicants also refer the examiner to the specification, Examples 1 to 4, at paragraphs [53] to [70], for additional examples, in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Accordingly, withdrawal of the enablement rejection is solicited.

Claim Rejection under 35 USC § 103:

On pages 6-10 of the office action, the examiner has maintained the obviousness rejection of claims 34-36 and 46-48 and alleged as being unpatentable over Price *et al.* (WO 98/15614) in view of Kistner *et al.* (US Patent 5,753,489), Luderer *et al.* (US P patent 4282315), Gauri *et al.* (US Patent 4,322,404) and Quest International Product Information, Norwich NY, 1995, and Sheffield Pharma Ingredients, Cell Nutrition, Hydrolyzed Proteins & Yeast Extracts, Technical Manual).

The examiner asserts that Price *et al.* at page 4-5 disclose that the plant extracts, including soy and yeast hydrolysates, are useful for replacing all components

of animals in culture medium. The examiner states that the current invention provides such an animal cell culture medium formulation (refers to page 6). The examiner further refers that page 22 discloses "the present invention also relates to methods for replacing or substituting animal-derived products with plant peptides, plant lipids, plant fatty acids, and/or enzymatic digests or extracts of yeast cells (or combinations thereof). Such plant and/or yeast-derived nutrients may be substituted for any number of animal-derived culture medium components or substituents...." Therefore, the examiner believes that the reference teaches the replacement of animal products in culture media by the disclosed plant and yeast hydrolysates.

In this context, applicants refers the examiner to the dictates of the MPEP:

> "...The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." ...., i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris,* 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) ...."
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> *See* MPEP § 2111 at 2100-37-38 (Rev. 6, September 2007).

Applicants reiterate that the claimed method requires that an "animal protein free" medium be used and not replacing or substituting animal-derived products, as the examiner was trying to impose the limitation from the specification into the claims, which is impermissible (see above).

In addition, the cited references do not motivate one skilled in the art to use an "animal protein free" medium in a method in combination with the other cited references to arrive at the claimed invention of an immunogenic composition comprising an "animal protein free" medium. Applicants also emphasize on the fact that by definition, unlike the media disclosed in the cited references, the instantly claimed "animal protein free medium" does not encompass recombinantly-produced animal proteins. Therefore, any combination of the cited references would not result in an immunogenic composition comprising "animal protein free" medium recited in the claims.

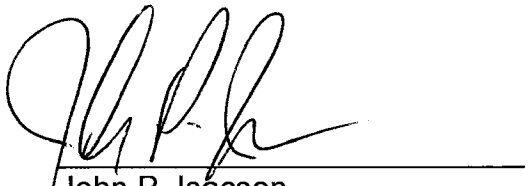
In view of the above, applicants submit that a *prima facie* case of obviousness

has not been established by the examiner. Accordingly, withdrawal of the rejection is earnestly requested.

REQUEST

Applicants submit that claims 34-36 and 46-66 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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